

(i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech pathologist who will provide the services to the particular individual;

(ii) Is periodically reviewed by a physician; and

(iii) Meets the requirements of § 410.63.

(3) They are furnished by a provider or by others under arrangements with, and under the supervision of, a provider.

(b) *Outpatient speech pathology services to certain inpatients of a hospital, RPCH, or SNF.* Medicare Part B pays for outpatient speech pathology services furnished to an inpatient of a hospital, RPCH, or SNF who requires them but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Excluded services.* No service is included as an outpatient speech pathology service if it would not be included as an inpatient hospital service if furnished to a hospital or RPCH inpatient.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 58 FR 30668, May 26, 1993]

§ 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

Notwithstanding the exclusion from coverage of vaccines (see § 405.310 of this chapter) and self-administered drugs (see § 410.29), the following services are included as medical and other health services covered under § 410.10, subject to the specified conditions:

(a) *Hepatitis B vaccine: Conditions.* Effective September 1, 1984, hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals who are at high or intermediate risk of contracting hepatitis B as listed below:

(i) *High risk groups.* (i) End-Stage Renal Disease (ESRD) patients;

(ii) Hemophiliacs who receive Factor VIII or IX concentrates;

(iii) Clients of institutions for the mentally retarded;

(iv) Persons who live in the same household as a hepatitis B carrier;

(v) Homosexual men;

(vi) Illicit injectable drug abusers; and

(vii) Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii).

(2) *Intermediate risk groups.* (i) Staff in institutions for the mentally retarded and classroom employees who work with mentally retarded persons;

(ii) Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work (including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions); and

(iii) Heterosexually active persons with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years).

(3) *Exception.* Individuals described in paragraphs (a) (1) and (2) of this section are not considered at high or intermediate risk of contracting hepatitis B if they have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B.

(b) *Blood clotting factors.* Effective July 18, 1984, blood clotting factors to control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

[55 FR 22790, Jun. 4, 1990; 55 FR 31186, Aug. 1, 1990]

§ 410.64 Services related to cardiac pacemakers and pacemaker leads.

(a) *Requirement.* (1) Physicians or providers that request or receive payment for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads, must submit to HCFA the information required for the pacemaker registry.

(2) The required information is set forth under 21 CFR part 805 of the FDA